Translation

PCT/JP2003/016417

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 3130WO0P	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/JP2003/016417	International filing date (*day/month/year*) 22 December 2003 (22.12.2003)	Priority date (*day/month/year*) 24 December 2002 (24.12.2002)
International Patent Classification (IPC) or national classification and IPC C12N 15/11, C12Q 1/68, A61K 39/395, 48/00, A61P 1/00, 11/00, 15/00, 35/00, G01N 33/15, 33/50, 33/574		
Applicant TAKEDA PHARMACEUTICAL COMPANY LIMITED		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:

      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☒ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) disk, 1 , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- ☒ Box No. I — Basis of the report
- ☐ Box No. II — Priority
- ☒ Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV — Lack of unity of invention
- ☒ Box No. V — Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI — Certain documents cited
- ☐ Box No. VII — Certain defects in the international application
- ☐ Box No. VIII — Certain observations on the international application

Date of submission of the demand 21 January 2004 (21.01.2004)	Date of completion of this report 02 December 2004 (02.12.2004)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2003/016417

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:

- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4)
- ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ The international application as originally filed/furnished

☐ the description:

pages _____, as originally filed/furnished
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____

☐ the claims:

pages _____, as originally filed/furnished
pages* _____, as amended (together with any statement) under Article 19
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____

☐ the drawings:

pages _____, as originally filed/furnished
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____

☒ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing *(specify)*: _____
- ☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing *(specify)*: _____
- ☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP03/16417

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 1, 10, 11, 18, 22-25

because:

☒ the said international application, or the said claims Nos. 22, 23, 24, 25 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

The inventions of claims 22-25 concern a method for treating the human body by therapy, which does not require an examination by the International Preliminary Examining Authority in accordance with PCT Article 17(2)(a)(i) and Rule 39.1(iv).

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 1, 10, 11, 18 are so unclear that no meaningful opinion could be formed *(specify)*:

(See the Supplemental Box)

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ see Supplemental Box for further details.

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	13, 19-21, 27	YES
	Claims	2-9, 12, 14-17, 26	NO
Inventive step (IS)	Claims	13, 19-21, 27	YES
	Claims	2-9, 12, 14-17, 26	NO
Industrial applicability (IA)	Claims	2-9, 12-17, 19-21, 26, 27	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Document 1: Nature 2002, Vol. 419, pp. 624-629
Document 2: WO 02/86443 A2 (EOS BIOTECHNOLOGY, INC.) October 31, 2002
Document 3: JP 2001-505402 A (BOEHRINGER INGELHEIM INT) April 24, 2001

Claims 2-9, 12, 14-17 and 26

1) Documents 1 and 3 describe performing a diagnosis of cancer using the EZH2 protein, which has the same sequence as SEQ ID NO: 1, or gene thereof, and the inhibition of cell growth in cancer using antisense RNA (for document 3, see page 15, top portion). Therefore, documents 1 and 3 describe the same constitution as the inventions of claims 2-4, 7, 8, 12, 14-17, and 26. In addition, this examination finds that persons skilled in the art can easily conceive of preparing a drug for the treatment of cancer from antibodies of the above protein in order to inhibit the expression of that gene.

2) Document 2, page 232 describes a protein (SEQ ID NO: 113) having the same sequence as SEQ ID NO: 1 of this application as a protein associated with lung cancer, and page 7 describes using a gene encoding the above sequence for diagnosis, or antibodies and antisense RNA thereof for treatment. Therefore, document 2 describes the same constitution as the inventions of claims 2-9, 12, 14-17, and 26.

Claims 13, 19-21 and 27

None of the documents cited in the international search report describes the inventions of claims 13, 19-21, and 27, and these matters are not obvious to persons skilled in the art.

Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date (valid claim) *(day/month/year)*
WO 03/12067 A2 [PX]	13.02.2003	02.08.2002	01.08.2001
WO 03/70887 A2 [PX]	28.08.2003	13.02.2003	20.02.2002

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure *(day/month/year)*	Date of written disclosure referring to non-written disclosure *(day/month/year)*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Supplemental Box Relating to Sequence Listing

Continuation of Box No. 1, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis that of:

   a. type of material

   ☒ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material

   ☐ in written format

   ☒ in computer readable form

   c. time of filing/furnishing

   ☐ contained in the international application as filed

   ☒ filed together with the international application in computer readable form

   ☐ furnished subsequently to this Authority for the purpose of search and/or examination

   ☐ received by this Authority as an amendment* on _____

2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

** If item 4 in Box No. I applies, the listing and /or table(s) related thereto, which form part of the basis of the report, may be marked "superseded".*

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of Box III:

The descriptions "compounds inhibiting activity" or "compounds having inhibitory action on enzymatic activity" in the inventions of claims 1, 10, 11 and 18 concern compounds that inhibit the activity of the protein defined in claims 1 and 10, and compositions containing compounds defined by these desirable properties. The description of the above compounds includes all compounds having such properties, but the Specification contains no description whatsoever of specific examples of the above compounds, and therefore the descriptions of these inventions lack full disclosure in the sense of PCT Article 5 and support by disclosure in the Specification in the sense of PCT Article 6. In addition, after consideration of the level of technical knowledge available at the time of filing, this examination finds that it is entirely unclear which specific compounds are included and which compounds are excluded from this description, and therefore the descriptions of the above claims are exceedingly vague and do not satisfy the requirement for clarity stipulated by PCT Article 6.